



NOV 23 2009

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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 6,355,245

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,355,245, which claims the human biologic drug product Soliris® (Eculizumab), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 735 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 735 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 4, 2009, (74 Fed. Reg. 9406), would be 771 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,177) + 183 \\ &= 771 \text{ days (2.1 years)}\end{aligned}$$

Since the regulatory review period began June 27, 2003, after the patent issued (March 12, 2002), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 771 days, would extend the patent from March 12, 2019 to April 21, 2021, which is beyond the 14-year limit (the approval date is March 16, 2007, thus the 14 year limit is March 16, 2021). The period of extension is thus limited to 735 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, March 12, 2019, to and including March 16, 2021, or 735 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension

determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,355,245
Granted:	March 12, 2002
Original Expiration Date <sup>1</sup> :	March 12, 2019
Applicant:	Mark J. Evans et al.
Owner of Record:	Alexion Pharmaceuticals, Inc.
Title:	Antibodies To Human Complement Component C5
Product Trade Name:	SOLIRIS® (Eculizumab)
Term Extended:	735 days
Expiration Date of Extension:	March 16, 2021

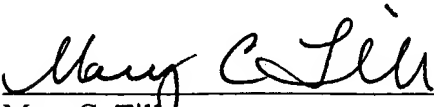
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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail:        Mail Stop Hatch-Waxman PTE  
                  Commissioner for Patents  
                  P.O. Box 1450  
                  Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

  
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Mary C. Till

Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc:     Office of Regulatory Policy  
         Food and Drug Administration  
         10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
         Silver Spring, MD 20993-0002

RE: Soliris® (Eculizumab)  
Docket No.: FDA-2007-E-0166

Attention: Beverly Friedman